Section II (Remarks)

A. Summary of Amendments

By the present amendment, claims 20-58 have been cancelled, and claims 59-95 are newly presented. Claims 1-19 were cancelled previously. Applicant has presented new claims 59-95 in lieu of amendments to the prior claims for the convenience of the Examiner, to reduce the number of independent claims, and to better organize each dependent claim as immediately following its related base claim. No excess claim fees are due since the numbers of both independent claims and total claims have been reduced by the foregoing amendments. Furthermore, no new matter within the meaning of 35 U.S.C. 132 has been introduced by the foregoing amendments.

B. Applicant's Summary of Examiner Interview Conducted on February 16, 2007

The undersigned extends thanks to the Examiner for making time for an in-person Examiner Interview on February 16, 2007. A summary of the interview follows. Various features of devices and apparatuses to potentially distinguish the cited Terentiev '856, Migule, Bibbo, and Jones references were discussed, including features such as non-rotation of the paddle, pattern of movement of the support rod and paddle, shape of the paddle, welded engagement between the sleeve and the bag/tank, and restraint of rotational movement of the paddle by the sleeve. No agreement with respect to the claims was reached.

C. Response to Claim Objections

In the October 30, 2006 Office Action, claims 36-38 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 36-38 have been cancelled herewith; accordingly, the objections to such claims are moot.

D. Response to Provisional Rejection For Double Patenting

In the October 30, 2006 Office Action, claim 33 was provisionally rejected for double patenting over claim 20 if claim 20 were found to be allowable. Claims 20 and 33 have been cancelled herewith; accordingly, the provisional double patenting rejection of claim 33 is now moot.

E. Response to Rejections Under 35 U.S.C. 102

In the October 30, 2006 Office Action, claims 41, 42, and 44 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,384,354 to Migule et al. ("Migule"). Such claims have been cancelled herewith; accordingly, the rejections of such claims are now moot. Discussion of Migule relative to the newly presented claims is provided below.

F. Response to Rejections Under 35 U.S.C. 103

In the October 30, 2006 Office Action, claims 20-27 and 29-58 were rejected under 35 U.S.C. 103, as being unpatentable for obviousness over U.S. Patent Application Publication No. 2002/00105856 to Terentiev ("Terentiev '856") in view of U.S. Patent Application Publication No. 2003/0226857 to Bibbo et al. ("Bibbo") and U.S. Patent No. 2,877,994 to Jones ("Jones"). Claims 20-27 and 29-58 have been cancelled herewith; accordingly, the rejections of such claims are now moot. Discussion of Terentiev '856, Bibbo, and Jones relative to the newly presented claims is provided below.

G. Disclosure of Cited References

1. Disclosure of Migule

Migule discloses an agitator for liquids, in which a closed container includes therein an agitator vessel containing a movable weight and a flexible hollow shaft extending through the container to the agitator vessel. Migule, col. 1, lines 12-21. The weight within the apparatus is adapted for circular or reciprocating movement by electrical or mechanical means passing through the hollow shaft. Id. (Embodiments directed to electrically-motivated movement are inapplicable to the present application to the extent that they lack any support rod extending through a sleeve). With regard to embodiments employing *mechanical means* for driving the weight, Migule states:

> The drive motor for the unbalanced rotating mass or the moved mass, respectively, can be … connected to the rotating or pendulously moving mass by means of an articulated or cardan shaft or a resiliently bendable shaft. (Migule, col. 2, lines 5-11.)
>
> * * *
>
> **A shaft 6 is guided, by a number of roller or plain bearings 7 in the tube** 4. An imbalance 10 is attached by an arm 9 to the bottom of the shaft 6. **When the shaft 6 rotates**, the imbalance 10 moves over a circular path inside the member 5. A drive motor 12 (shown diagrammatically) is disposed above the cover 2 to drive the shaft 6. (Migule, col. 2, lines 60-66.)

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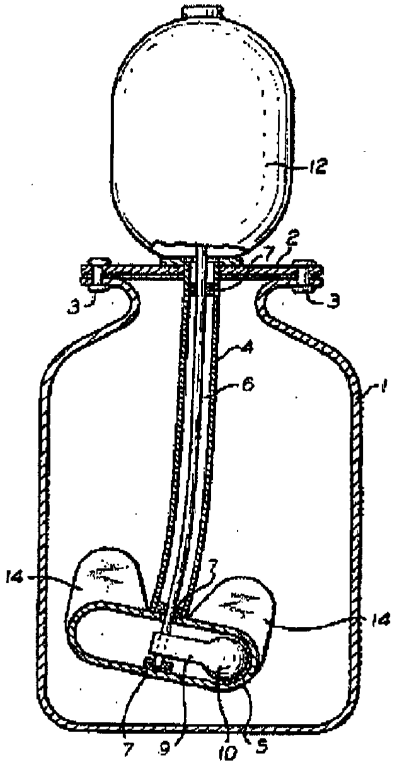
The movement of the weight causes an imbalance in the agitator vessel, causing it to move through the liquid for mixing the liquid. *Id.*, col. 1, lines 21-23. Migule later refers to the flexible hollow shaft simply as a **tube**. E.g., Migule, col. 2, "the **agitator member itself comprises suitably a tube which is made of a material resilient to bending**, such as metal or plastics, and which is **rigidly connected**, for example by welding to the cover or wall of the agitator container." *Id.*, col. 2, lines 25-29. Further with regard to the "resilient" nature of the tube, *see*: Migule, col. 2, lines 54-57 "[a] **tube** 4 is made of a **resilient** material, for instance a **steel tube** ... " and col. 2, lines 72 – col. 3, line 5: "[Figure 1] shows only one of the positions through which the agitator device passes when the imbalance 10 is rotating, the resilient tube 4 and the resilient shaft 6 being **flexed**, whereas, when the imbalance 10 is not rotating, the agitator is in the central position in which the tube 4 and the shaft 6 are substantially straight."

Figure 1 of Migule is reproduced below for ease of reference.

FIG. 1



Regarding the "tube 4" that Migule teaches is "*resilient to bending*," Merriam-Webster's Online Dictionary defines "**resilient**" as "characterized or marked by resilience,"[1] with "resilience" being defined by the same source as "the **capability of a strained body to recover its size and shape after deformation caused especially by compressive stress.**"[2] Thus, while the tube 4 of Migule is capable of bending, it has sufficient rigidity to recover its shape following flexure.

Migule thus teaches (1) the use of a "resilient [hollow] tube 4" (*e.g.*, a steel tube) that is "rigidly connected ... to the cover or wall of the agitator container," wherein this hollow (outer) tube 4 contains (2) a rotating (internal) shaft 6 that drives the weight 10 to cause the hollow tube 4 to flex due to the rotation of the weight driven by the shaft 6.

Nothing in Migule discloses (1) any "mixing bag," (2) any paddle within a sleeve welded to a mixing bag, (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve.

2. *Disclosure of Terentiev '856*

Terentiev '856 discloses a mixing bag 12 containing a spiral-shaped rotatable flexible or rigid tube 14, 140 that serves as a mixer. The rotatable tube extends through a first seal 18, 118, and optionally a second seal 119, defined in a wall of the bag, and engages an external motor 20. Terentiev '856, FIGS. 1-2 and corresponding text (as reproduced below), including ¶ [0019].

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[1] Source: http://www.m-w.com/dictionary/resilient

[2] Source: http://www.m-w.com/dictionary/resilience

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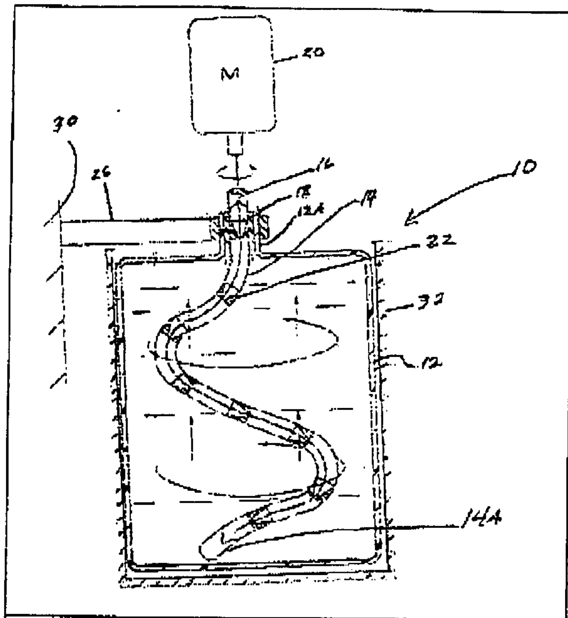
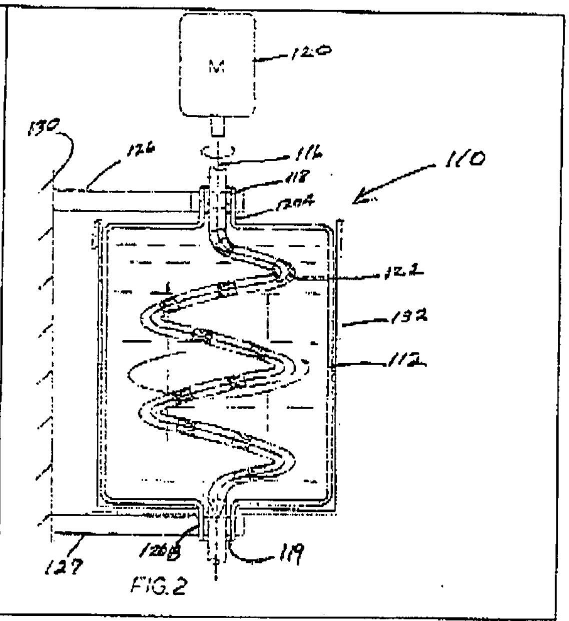


Terentiev '856 Figure 1



Terentiev '856 Figure 2

"As with the first [seal 18], the **static seals** 118, 119 can be made out of a rigid plastic similar to polyethylene, ceramic, or a metal similar to stainless steel." Id., ¶ [0019]. The neck(s) 12A, 120A, 120B of a mixing bag are clamped around the seal(s) with clamp mechanism(s) 26, 126, 126. Id., ¶¶ [0017], [0019] & FIGS. 1-2. The resulting clamped structure provides an interface between the hollow mixing tube and the tank in which the tube freely rotates against the static seals 18, 118, 119. Consistent with this utility, "the tube 14 has an opened distal end, outside the container 12, a closed distal end, inside the container 12 and an **essentially a circular cross-section of constant diameter along its length**." Id., ¶ [0015]. A rigid rod 16 is inserted into the tube 14, such that the flexible tube takes on the shape of the rod. Id., ¶¶ [0009], [0015]. Spacers 22 [and 122] are provided along the length of the inner wall of the tube 14 to, *inter alia*, "assist in ... **transferring the movement [or rotational torque energy] of the rod 16 to the tube** during operation ... by transmitting rotational torque energy ." Id., ¶ [0016]. The spacers 22, 122 have a conically-shaped "bore 22a to facilitate the feeding or threading of rod 16 through the tube 14 without damage thereto ... ." Id., ¶ [0016] "The rod is operatively coupled to a drive shaft of a motor and during operation **causes the flexible mixing tube to move [i.e., rotate] with the rod** for axial or radial mixing of the product contained within the bag." Id., ¶ [0009].

"For radial mixing, a zigzag shape or "S" shape of the rod 16 is the preferred embodiment." Id., ¶ [0015]. For axial mixing, a "helically shaped rod 116" may be used. Id., ¶¶ [0018], [0019]. The rod should "have its mass distributed equally about it[s] **axis of rotation** to minimize ... vibrations ... during any mixing process." Id., ¶ [0015].

The Examiner has already conceded that Terentiev '856 fails to recite any sleeve welded to a bag, or any mixing paddle. October 30, 2006 Office Action, page 5.

Nothing in Terentiev '856 discloses (1) any mixing paddle having a widened portion (or any cavity having a corresponding widened portion), (2) any sleeve welded to a mixing bag, (3) any coupling guide defining an aperture sized to permit pivotal arrangement of the support rod between a kinetic energy source and a mixing bag, or (4) a non-rotating support rod within a sleeve.

3. *Disclosure of Jones*

The Examiner has cited Jones as teaching a shaft having at its end "an enlarged, broad paddle element" that "is enclosed about a sleeve C to provide a sealed protection of the mixing element B." October 30, 2006 Office Action, page 5. In truth, Jones teaches that a *turnable shaft may be bent or otherwise twisted* into various shapes for use in agitating machines. **No matter what shape into which the turnable shaft is formed, however, its diameter or cross-sectional width remains the same**.[3] In one embodiment described in connection with Figs. 4-5, Jones describes the addition of "discs F" of larger diameter than the shaft B, but such "circular discs F are secured to the flexible sleeve C" – which means that the discs F are **exterior to the sleeve C** and thus are NOT isolated from the contents of any mixing chamber. **Jones provides no teaching or derivative basis for modifying such shaft to add a widened paddle *within the sealed sleeve***. To the contrary, Jones teaches that the **shaft should rotate within the sleeve** (e.g., col. 2, lines 12-16, "although [the sleeve is] twisted or distorted to some extent by being carried around the shaft [it] does periodically untwist itself notwithstanding continued rotation of the [shaft]"). Any rotating broad paddle disposed within the sleeve of Jones would interfere with such operation.

Nothing in Jones discloses (1) a mixing bag, (2) any paddle within a sleeve welded to a mixing bag; (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve.

4. Disclosure of Bibbo

Bibbo teaches a mixing assembly, but in each instance it teaches the use of an impeller that directly contacts the components to be mixed **without any interposing sleeve**. In this regard, Bibbo's disclosure is indistinct from any other conventional mixer.

Nothing in Bibbo discloses (1) any sleeve welded to a mixing bag; (2) any paddle within a sleeve; (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve.

H. Distinctions of New Claims Over the Cited References

New claims 59-95 include four independent claims, namely, independent claims 59 and 69 each drawn to a mixing container, claim 70 drawn to a mixing apparatus, and claim 88 drawn to a mixing method. Such independent claims are reproduced below.

> 59. (New) A mixing container comprising:
> a hollow mixing bag having at least one interior wall;
> a mixing paddle adapted to engage a support rod mechanically coupleable to receive kinetic energy from a kinetic energy source, the mixing paddle having at least one widened paddle portion that is wider than a nominal diameter or cross-sectional width of the support rod;
> a coupling guide joined to the mixing bag, the coupling guide defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag; and
> an integral sleeve sealingly and permanently welded proximate the coupling guide aperture to any of the bag and the coupling guide, the sleeve having a closed end protruding into the interior of the hollow bag, having at least one exterior wall, and defining a cavity containing the mixing paddle, the cavity

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[3] See, e.g., Jones Figs. 1-5 (depicting constant diameter shaft C) & claims 1-3 ("shaft having a turnable portion extending through a chamber wall, and intermediate cranked portion … and a curved agitator portion").

having at least one widened cavity portion disposed about the at least one widened paddle portion;

wherein the at least one interior wall of the mixing bag and the at least one exterior wall of the sleeve encloses a volume, and the sleeve serves as an isolation barrier between the volume and the mixing paddle.

69. **(New)** A mixing container comprising:

a hollow mixing bag having at least one interior wall, the mixing bag comprising a substantially transparent polymeric film material and having a resealable access port;

a mixing paddle adapted to engage a support rod mechanically coupleable to receive kinetic energy from a kinetic energy source, the mixing paddle having at least one widened paddle portion that is substantially broader than a nominal diameter or cross-sectional width of the support rod;

a coupling guide joined to the mixing bag, the coupling guide defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag; and

an integral sleeve comprising a substantially transparent polymeric film material, the sleeve (1) being sealingly and permanently welded proximate the coupling guide aperture to any of the bag and the coupling guide, (2) having a closed end protruding into the interior of the hollow bag, having at least one exterior wall, and (3) defining a cavity containing the mixing paddle, the cavity having at least one widened cavity portion disposed about the at least one widened paddle portion;

wherein the polymeric film material of the mixing bag has substantially the same composition as the polymeric film material of the sleeve, the at least one interior wall of the mixing bag and the at least one exterior wall of the sleeve encloses a volume, and the sleeve serves as an isolation barrier between the volume and the mixing paddle.

70. **(New)** A mixing apparatus comprising:

a kinetic energy source;

a hollow mixing bag having at least one interior wall and a substantially central vertical axis;

a support rod mechanically coupleable to receive kinetic energy generated by the kinetic energy source;

a mixing paddle;

a flexible integral sleeve protruding into the interior of the hollow mixing bag, having at least one exterior wall, and defining a cavity containing the mixing paddle and at least a portion of the support rod;

wherein the at least one interior wall of the mixing bag and the at least one exterior wall of the sleeve encloses a volume, with the sleeve serving as an isolation barrier to isolate the volume from the mixing paddle and the support rod; and

wherein the mixing paddle contained within the sleeve is driven by the support rod when coupled to the kinetic energy source and, when so coupled, is adapted to travel within the bag through a defined path at a nonzero angle relative to the central vertical axis without continuous rotation of the support rod about a longitudinal axis defined by the support rod.

88. **(New)** A mixing method employing a mixing apparatus including (1) a kinetic energy source, (2) a hollow mixing bag having a flexible integral sleeve joined thereto with a closed end of the sleeve protruding into the mixing bag, and (3) a mixing paddle enveloped by the sleeve and adapted to receive a support rod coupleable to the kinetic energy source, wherein at least one interior wall of the bag and an exterior wall of the sleeve defines an interior volume, and the sleeve serves as an isolation barrier between the interior volume and the mixing paddle, the method comprising the steps of:

supplying at least two components of a mixture to the interior volume;

engaging the support rod between the kinetic energy source and the mixing paddle;

mixing the at least two components by moving the enveloped mixing paddle in a closed curvilinear path within the interior volume without continuous rotation of the support rod about a longitudinal axis defined by the support rod to combine the at least two components and form said mixture.

The failure of each of the cited references to disclose certain key claim limitations has been discussed hereinabove. To summarize such discussion:

- **Migule** fails to disclose (1) any "mixing bag," (2) any paddle within a sleeve welded to a mixing bag, (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve;

- **Terentiev '856** fails to disclose (1) any mixing paddle having a widened portion (or any cavity having a corresponding widened portion), (2) any sleeve welded to a mixing bag; (3) any coupling guide defining an aperture sized to permit pivotal arrangement of the support rod between a kinetic energy source and a mixing bag, or (4) a non-rotating support rod within a sleeve;

- **Jones** fails to disclose (1) a mixing bag, (2) any paddle within a sleeve welded to a mixing bag; (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve; and

- **Bibbo** fails to disclose (1) any sleeve welded to a mixing bag; (2) any paddle within a sleeve; (3) any coupling guide joined to a mixing bag and defining an aperture sized to permit pivotal arrangement of the support rod between the kinetic energy source and the mixing bag, or (4) any non-rotating support rod disposed within a sleeve

Given these clear differences between the independent claims and the preceding references, new claims 59-95 are patentably distinguished over the cited art.

CONCLUSION

Claims 59-95 as provided herein are fully patentable distinguished over the cited art, and are in form and condition for allowance. Issuance of a Notice of Allowance is earnestly solicited. If, incident to formal issuance of a Notice of Allowance, any minor issues amenable to telephonic clarification or resolution should arise, the Examiner is encouraged to contact the undersigned attorney at (919)419-9350 to resolve such issues without delay.

Respectfully submitted,

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